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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ZYDUS PHARMACEUTICALS USA, INC., Plaintiff, v. ELI LILLY AND COMPANY, Defendant.	CIVIL ACTION NO: **COMPLAINT**

Plaintiff, Zydus Pharmaceuticals USA, Inc. (hereinafter "Zydus"), by and through its undersigned counsel, brings this action against Defendant Eli Lilly and Company ("Lilly") to obtain, *inter alia*, a judgment declaring that Zydus has the right to manufacture, use, offer to sell and sell within the United States, or import into the United States, generic atomoxetine in accordance with Zydus's fully approved Abbreviated New Drug Application ("ANDA") No. 79-017, which drug is marketed by Lilly under the brand name Strattera®, on the grounds, *inter alia*,

that there is no prohibition against Zydus bringing its generic atomoxetine immediately to market nor would Zydus be infringing Lilly's patent covering Strattera® because this patent has been declared invalid by this same Court in a different action. As such, as and for its Complaint against Lilly, Zydus respectfully alleges as follows:

PARTIES

1. Plaintiff Zydus is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business located at 73, Route 31 North, Pennington, NJ 08534.

2. Defendant Lilly is a corporation organized and existing under the laws of the State of Indiana, with a principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §1332 inasmuch as full complete diversity exists between Zydus, a New Jersey corporation with a principal place of business located at 73 Route 31 North, Pennington, NJ 08534, and Lilly, an Indiana corporation with a principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

4. Venue is appropriate pursuant to 28 U.S.C. §1391(a) and (c) inasmuch as Lilly resides in this district.

FIRST CLAIM – DECLARATORY JUDGMENT

5. On or about September 5, 2007, Lilly commenced an action in the United States District Court for the District of New Jersey captioned *Eli Lilly and Company v. Actavis Elizabeth LLC, et al.*, Civil Action No. 07-3770 (DMC) (the "*Actavis Action*").

6. In the *Actavis Action*, Lilly alleged, among other things, that Zydus and numerous other defendants infringed Lilly's United States Patent No. 5,658,590 (sometimes referred to herein as the "'590 Patent") by filing ANDA applications with the United States Food and Drug Administration (FDA) seeking FDA approval to market each of the defendants' own generic versions of Lilly's Straterra.®

7. In early December 2007, Lilly and Zydus agreed to resolve the *Actavis Action* via a Consent Judgment and Order (the "Consent Judgment").

8. The Consent Judgment was entered as an Order of the Court on December 12, 2007. (A true and correct copy of the Consent Judgment is attached hereto as Exh. A).

9. The Consent Judgment provides in pertinent part as follows:

> Based upon the stipulations of these parties as set forth herein, as to which the Court expresses no findings or conclusions, Zydus, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are

> hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any of the generic atomoxetine hydrochloride products defined by ANDA 79-017 ***during the life of the '590 patent***, including any extensions (including under 35 U.S.C. § 156 and including periods of regulatory exclusivity associated with the patent, such as pediatric exclusivity under 21 U.S.C. § 355a), absent authorization by Lilly.

(Consent Judgment, Exh. A at p.3, ¶ 1) (emphasis added).

10. After the entry of the Consent Judgment, the *Actavis Action* was fully litigated by one or more of the other named defendants through trial until the entry of judgment in August 2010. Zydus, however, was no longer a party to the *Actavis Action* after it had settled with Lilly via the Consent Judgment in December 2007.

11. After a six (6) day bench trial conducted in May 2010, the Hon. Dennis M. Cavanaugh issued a seventy four (74) page opinion in which he concluded, among other things, that "the '590 Patent is invalid for lack of enablement/utility under 35 U.S.C. § 112." (August 12, 2010 Opinion, Case No. 07-CV-03770, docket entry no. 657, at pg. 74).

12. On August 24, 2010, a judgment was entered in the remaining defendants' favor in the *Actavis Action.*

13. As a result of the District Court's entry of judgment in the *Actavis Action* determining the '590 Patent was invalid, the life of Lilly's '590 patent has

come to an end, and the '590 patent in no longer enforceable, unless the patent is revived upon appeal.

14. Lilly appealed the judgment on August 25, 2010 (the "Appeal"). On September 1, 2010, the United States Court of Appeals for the Federal Circuit Court issued an injunction as requested by Lilly, in Lilly's favor, prohibiting the parties to the Appeal from introducing/launching in the marketplace defendants' own generic versions of Lilly's patented form of the drug *(i.e.*, Straterra) pending disposition of Lilly's appeal (sometimes referred to hereinafter as the "Injunction").

15. Lilly belatedly recognizing that the injunction it had sought did not cover Zydus, that is becoming aware that Zydus, as a non-party to the Appeal, was not covered or otherwise restricted by the Federal Circuit's Injunction, filed a motion with the Federal Circuit on or about September 3, 2010 seeking to amend the official case caption so as to add Zydus as a named defendant-appellee. The Federal Circuit denied Lilly's motion on or about September 17, 2010.

16. Zydus is no longer a party to the Actavis Action nor is it by extension a party to Lilly's pending Federal Circuit Appeal. Consequently, Zydus is not barred by the Federal Circuit's Injunction from marketing its generic atomoxetine in the United States during the pendancy of Lilly's appeal.

17. The Consent Judgment only prohibits Zydus from marketing its generic atomoxetine during the ***life of the '590 patent.*** Since the '590 Patent has been declared invalid by this Court, Zydus is entirely within its rights, like any other person or entity not expressly enjoined by the Federal Circuit Injunction, and who has FDA approval to do the same, to immediately manufacture, use, offer to sell and sell within the United States, or import into the United States, generic atomoxetine hydrochloride products, including those defined by Zydus's ANDA 79-017.

18. Despite the Federal Circuit's rejection of Lilly's back-door attempt to reintroduce Zydus as a party-defendant/appellee to the Appeal, Lilly has threatened action against Zydus maintaining: (i) that Zydus is bound by the Federal Circuit Injunction; and, (ii) that any potential efforts by Zydus to market generic atomoxetine hydrochloride products (including those defined by Zydus's ANDA 79-017) would violate the terms of both the Federal Circuit's Injunction and the Consent Judgment.

19. An actual and justiciable controversy exists between Zydus and Lilly regarding: (i) that Zydus is bound by the Federal Circuit Injunction; and, (ii) that any potential efforts by Zydus to market generic atomoxetine hydrochloride products (including those defined by Zydus's ANDA 79-017) would violate the terms of both the Federal Circuit's Injunction and the Consent Judgment.

20. By reason of the foregoing, Zydus seeks a declaratory judgment that Zydus is entirely within its rights, in its sole discretion and without any bar imposed by the Federal Circuit's Injunction and/or Consent Judgment, to immediately manufacture, use, offer to sell and sell within the United States, or import into the United States, generic atomoxetine hydrochloride products, including those defined by Zydus's ANDA 79-017.

Prayer for Relief

WHEREFORE, Plaintiff Zydus Pharmaceuticals USA, Inc. requests entry of judgment in its favor and against Defendant Eli Lilly and Company as follows:

(a) that Zydus may proceed, in its sole discretion and without any bar imposed by the Federal Circuit's Injunction and/or Consent Judgment, to immediately manufacture, use, offer to sell and sell within the United States, or import into the United States, generic atomoxetine hydrochloride products, including those defined by Zydus's ANDA 79-017; and

(b) such other, further and different relief as the Court deems just and equitable.

Dated: October 27, 2010

KELLEY DRYE & WARREN LLP

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, Plaintiff, v. ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., USA, SUN PHARMACEUTICAL INDUSTRIES LIMITED, SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC. Defendants.	Civil Action No. 07-3770 (DMC)

CONSENT JUDGMENT AND ORDER

Pursuant to the stipulation and consent of Plaintiff Eli Lilly and Company ("Lilly") and Defendant Zydus Pharmaceuticals, USA, Inc. ("Zydus"), this Court hereby issues the following Consent Judgment And Order.

Stipulated Facts

1. Lilly brought this civil action against Zydus in this Court on September 5, 2007, charging Zydus with infringement of its United States Patent No. 5,658,590.

2. This Court has subject matter jurisdiction over this patent infringement action and personal jurisdiction over Lilly and Zydus. Venue is proper in this Court as to Lilly and Zydus.

3. United States Patent No. 5,658,590 is neither invalid nor unenforceable.

4. Zydus submitted Abbreviated New Drug Application ("ANDA") 79-017 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use, and sale of the atomoxetine hydrochloride products described therein prior to the expiration of the '590 patent, including any extensions (including under 35 U.S.C. § 156 and including periods of regulatory exclusivity associated with the patent, such as pediatric exclusivity under 21 U.S.C. § 355a).

5. The use of the atomoxetine hydrochloride products defined by ANDA 79-017, as directed by Zydus' proposed labeling and package inserts for such products, falls within the scope of one or more claims of the '590 patent, as properly construed.

6. Lilly is entitled to a permanent injunction enjoining Zydus, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any of the atomoxetine hydrochloride products defined by ANDA 79-017 during the life of the '590 patent, including any extensions (including under 35 U.S.C. § 156 and including periods of regulatory exclusivity associated with the patent, such as pediatric exclusivity under 21 U.S.C. § 355a), absent authorization by Lilly.

Consent Judgment And Order

Accordingly, pursuant to the stipulation and consent of Lilly and Zydus and the above stipulated facts, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. Based upon the stipulations of these parties as set forth herein, as to which the Court expresses no findings or conclusions, Zydus, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any of the generic atomoxetine hydrochloride products defined by ANDA 79-017 during the life of the '590 patent, including any extensions (including under 35 U.S.C. § 156 and including periods of regulatory exclusivity associated with the patent, such as pediatric exclusivity under 21 U.S.C. § 355a), absent authorization by Lilly.

2. Lilly and Zydus expressly waive their right to appeal or otherwise move for relief from this Consent Judgment And Order.

3. This Court retains jurisdiction over Lilly and Zydus for purposes of enforcing this Consent Judgment And Order.

4. This Consent Judgment And Order shall finally resolve this action between Lilly and Zydus. Each party shall bear its own fees and costs in connection with this action, including attorney fees.

5. The Clerk of the Court is directed to enter this final judgment forthwith.

IT IS SO ORDERED this 12 day of December, 2007.

IT IS SO ORDERED this 12 day of Dec, 2007.

THE HONORABLE DENNIS M. CAVANAUGH
United States District Judge
District of New Jersey

STIPULATED AND CONSENTED TO BY:

ELI LILLY CORPORATION

By: Laura A. Armitage JPL

Title: Sr. V.P. and General Counsel

Date: December 5, 2007

ZYDUS PHARMACEUTICALS, USA INC.

By: _____

Title: _____

Date: _____

THE HONORABLE DENNIS M. CAVANAUGH
United States District Judge
District of New Jersey

STIPULATED AND CONSENTED TO BY:

ELI LILLY CORPORATION

By: _____

Title: _____

Date: _____

ZYDUS PHARMACEUTICALS, USA INC.

By: _____

Title: CEO

Date: 12-05-07